AUG 0 6 2002

510(k) Summary

ADC Dental

K021542

Common/Classification Name: Computed Radiography, 21 CFR 892.1630

Agfa Corporation
10 South Academy Street
Greenville, SC 29602-9048

Contact: Jeff Jedlicka, Prepared: May 8, 2002

A. LEGALLY MARKETED PREDICATE DEVICES

The predicate device is the previous version of the same device, namely the ADC Compact Plus, which was cleared by FDA on 28 September 2001 as K013138. For the indications for use of acquiring digital dental/maxillofacial radiographic images, the **ADC Dental** is substantially equivalent to the Schick Technologies CDR-Pan Model 4700, which was cleared for marketing by FDA on December 11, 1998 as K982661.

B. DEVICE DESCRIPTION

The ADC Compact Plus, the predicate device, is a computed radiography imaging system. Instead of screens and photographic film for producing the diagnostic image, the ADC Compact system utilizes an "imaging plate," a plate coated with photo-stimulatable storage phosphors that are sensitive to X-rays and capable of retaining a latent image. This imaging plate is inserted into a device that scans it with a laser and releases the latent image in the form of light which is converted into a digital bit stream. The bit stream of image data is stored locally and can also be stored in the PACS network in DICOM format.

The **ADC Dental** is identical in hardware and software to the ADC Compact Plus. The only difference is in a data file provided that is accessed by the (unchanged) software, where preselected image processing parameters are paired with typical dental exposure parameters by exam type. Rather than entering the exposure parameters manually, as would be the case for dental/maxillofacial exams using the ADC Compact Plus, the user would simply select the exam type and patient age, and the proper image processing parameters would be selected automatically and applied to "developing" the image.

C. INTENDED USE

K011542

The ADC Dental is indicated for use to provide diagnostic quality images to aid in physician and dentist diagnosis. The ADC Dental is intended to be used in extraoral dental and maxillofacial imaging applications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **ADC Dental** has similar indications for use as the legally marketed predicate devices. The differences do not affect the intended diagnostic effect. The **ADC Dental** has the same (identical) technological characteristics as the predicate device. This premarket notification has described the characteristics of the **ADC Dental** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics are identical in the proposed and predicate devices.

F. TESTING

The ADC Dental was tested in a clinical environment and it was found to be preferred to traditional imaging techniques.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

Mr. Jeff Jedlicka
Manager of Regulatory Affairs
and Compliance
Agfa Corporation
10 South Academy Street
GREENSVILLE SC 29602

Re: K021542
Trade/Device Name: ADC Dental
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: May 9, 2001
Received: May 10, 2002

Dear Mr. Jedlicka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K021542

Device Name: ADC Dental

Indications For Use:

The ADC Dental is indicated for use to provide diagnostic quality images to aid in physician or dentist diagnosis. The ADC Dental is intended to be used in extraoral dental and maxillofacial imaging applications.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021542